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(71)(72) Applicant and Inventor: OLLIFFE, Robert, Malcolm [GB/GB]; 1 The Betchworth, Reigate Road, Betchworth, Surrey RH3 7ET (GB).

(74) Agent: WOODCRAFT, David, Charles; Brookes & Martin, High Holborn House, 52/54 High Holborn, London WC1V 6SE (GB).

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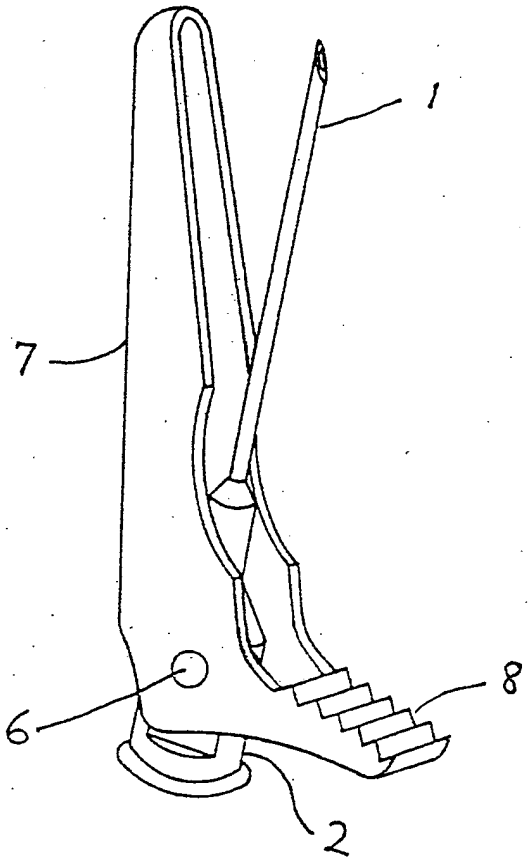
(54) Title: HYPODERMIC SYRINGE

(57) Abstract

A hypodermic syringe is described in which the needle (1) is protected by a guard. The guard includes a needle shroud (7) which is pivotable between open and closed positions and includes releasable locking means (9, 10, 12, 26, 31, 42, 43 and 44) to hold the guard respectively in open and closed positions. An operating arm (8) is attached to the needle shroud (7) to facilitate pivoting of the shroud from the open to the closed positions. Generally, shroud (7) is integrally moulded with arm (8) and needle boss (25) or with a sleeve (24) which can be fitted over boss (25).



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HYPODERMIC SYRINGE

This invention relates to hypodermic syringes and in particular provides a syringe which is safer in use.

Because of the growing prevalence of serious diseases which are spread by contact with infected blood, e.g. infectious hepatitis and human immunodeficiency virus (HIV), it is important to dispose safely of hypodermic syringes after use. Conventional practice is to supply needles separately packaged in a sealed tubular sheath. The needle can then be screwed onto a standard syringe barrel and the sheath removed to expose the needle for use.

After the injection has been given or the sample taken from the patient, the sheath is often replaced on the needle and the whole syringe placed in a disposal box for destruction. Unfortunately, the person administering the injection may accidentally touch the end of the needle, particularly when attempting to replace the sheath.

There is consequently a need to provide a safer method of protecting the needles of syringes, particularly after use.

According to the present invention there is provided a hypodermic syringe having a needle guard which is pivotable between a first position in which it covers the tip of the needle and a second position in which the needle tip is exposed and the guard lies in a position which does not interfere with the use of the syringe.

Normally, the guard will include locking means for releasably holding it in said first and/or second positions. Particularly, when the guard is manufactured in a plastics material, such locking means preferably includes projections or recesses which engage corresponding recesses or projections formed in the base support for the needle or the needle boss.

Pivoting the needle guard between the second and first positions is conveniently achieved by application of finger pressure to a lever extension arm of the guard.

The needle guard is preferably moulded together with its operating arm and the needle boss of the syringe as a single entity or with a fitting, such as a sleeve, which can be slid over a standard needle boss.

Further features and advantages of the syringe of the present invention will become apparent from the following description and accompanying drawings in which:-

Figure 1 is a perspective view of one embodiment of a hypodermic syringe needle fitted with a guard in accordance with the invention,

Figure 2 is a section through the guard and needle showing in solid lines the guard in its first, closed position and in its second, open position in broken lines,

Figure 3 is a section similar to Figure 2,

Figure 3A is a section through the guard,

Figure 4 is a section taken on the line A-A in Figure 3,

Figure 5 is a perspective view of the needle assembly

with the guard removed,

Figure 5A is a perspective view (partly sectioned) of the guard,

Figures 6A to D are various views of a second embodiment of the invention which includes an integrally moulded sleeve for attachment to a needle boss,

Figures 7A to C are views of a third embodiment of the invention in which the needle guard includes an integrally moulded needle boss,

Figures 8A to G are several views of a fourth embodiment of the invention, Figures 8E to G illustrating its operation,

Figures 9A to N are views of a fifth embodiment of the invention in which the needle guard is moulded integrally with the needle boss.

Referring to the drawings and particularly Figure 1, the needle and guard assembly comprises a needle 1 of standard design and dimensions which is supported by a moulded plastics boss 2. Boss 2 is generally of standard form in so far as it is designed to be fitted at its lower portion 4 to a conventional hypodermic syringe barrel (not shown) and is sealed to the lower end 3 of the hollow needle 1 in an upper portion 5 of reduced diameter (see Figure 4). Moulded to the outside of base portion 4 is a pair of trunnions 6 on which a needle shroud 7 is pivotally mounted and constitutes the effective part of the guard.

Shroud 7 (and also needle boss 2) are preferably injection moulded from a thermoplastics material. As best seen in Figure 1, shroud 7 has a generally trough-shaped form and in its closed position, shrouds the needle on three sides and covers the tip.

An extension arm 8 is integrally moulded with the main body of the shroud 7 and facilitates pivoting of the guard from its open, operative position as shown in broken lines in Figure 2, to its closed, protective position, shown in broken lines in Figure 3.

Locking of the shroud in the open and closed positions may be achieved by cooperating features moulded in the shroud 7 and the boss 2. These may take the form of projections moulded on one of these components which engage with a corresponding recess in the other component. Thus, the shroud 7 may be moulded with a projection 9 which is adapted to be a snap fit into a corresponding recess 10 formed in the boss when the shroud is pivoted into the closed position. Similarly, the shroud may be moulded with a similar projection 11 which is adapted to form a snap fit with a recess 12 when the shroud is pivoted into its open position.

It will be appreciated that other devices may be moulded to the shroud and/or needle boss to retain the guard in the closed and operative positions. For example, the walls of the shroud may be tapered in thickness so that when pivoted in one position, the shroud is pressed more tightly against the boss.

It may also be desirable to provide some means to prevent re-use of the syringe. This may be achieved, for example, by moulding a resilient finger of fingers to the inside faces of the shroud. The finger is normally trapped between the boss and the inner wall of the shroud but when the shroud is closed and pivoted into an 'over-centre' position, the finger is released and engages with a recess in the boss, thus preventing removal of the guard and re-use of the needle.

As best seen in Figure 5A, the guard is moulded with holes 13 to receive trunnions 6 and a tapered lead slot 14 so that in manufacture the moulded shroud 7 can be pushed onto the trunnions 6. A thermoplastics material is chosen which has sufficient flexibility that the trunnions will ride up the lead slot 14 and snap into holes 13.

After assembly of the guard onto the needle, the resulting assembly may be packaged in a sterile pack, such as a shrink-wrap film, and provided with a tear-strip to ease removal of the film prior to use.

Figure 6A is a perspective view of an embodiment in which the needle guard is moulded integrally with a sleeve which is adapted to fit over a needle boss. The needle shroud portion 7 has an operating arm 8 attached to one side by a flexible strap 20. On the side remote from strap 20, shroud 7 is attached to a sleeve 21 by a plastic hinge 22. The end of arm 8 remote from shroud 7 is also attached by a flexible hinge 23 to second sleeve 24. Sleeves 23 and 24 are internally shaped and dimensioned so

that they fit over a standard needle boss and are anchored tightly thereon. As shown in Figure 6D, the elements of the guard are flexibly interconnected and can be readily manufactured as a single moulding, e.g.by injection moulding.

Figures 6B and 6C show the manner in which the guard is operated. The guard is desirably packaged together with the needle and its attached boss in the manner shown in Figure 6C. A syringe body can then be attached to the needle boss in the usual way and any packaging film or outer packaging removed from the needle guard/needle assembly. Needle shroud 7 is then gripped and pivoted into the position shown in Figure 6B. In this position, the syringe is filled with the medication to be administered and the injection given or the sample taken from the patient. At this stage, the tip of the needle is contaminated with blood and the needle shroud 7 is snapped back into the guarded position shown in Figure 6C by downward thumb pressure on the arm 8 without any risk of touching the tip. The guarded needle can then be discarded safely while the tip continues to be protected by the shroud 7. Strap 20 is provided with a slot and opening 26 into which the upper part of the boss 25 engages when the needle shroud is in its open position (Figure 6B), so as to hold the shroud steady in this position. Similarly, the lower part of the needle shroud may be shaped so as to engage the needle boss in the closed position. One or more corresponding protrusions

and recesses 27 and 28 may be formed on the sleeves 21 and 24 in order to inhibit twisting of the sleeves on the needle boss.

Figures 7A, B & C illustrate a modification of the embodiment of Figures 6A, B, C & D in which the main difference is that a needle boss is moulded integrally as part of the guard. The same reference numerals are used to indicate parts in this embodiment which are the same or similar to those in the Figure 6A embodiment. Figure 7A shows the needle guard in the initial and final closed positions in full lines and in its open position in broken lines. The method of operating the needle guard and using the syringe is essentially identical to that described in connection with Figure 6A, B, C & D. Referring to Figure 7A, this shows the most convenient configuration for moulding the needle guard. As can be seen, a needle boss 25 is connected by an integral flexible strap 29 to arm portion 8. Needle boss 25 is similar to standard needle bosses except that it incorporates an anchor point 30 for attachment of the integral strap 29. Figure 7C shows in plan view a part of the moulding of Figure 7B. Aperture 26 is connected to slot 26a via a throat which resiliently retains the needle shroud in its open position. The restricted width of slot 26a compared with diameter 31 also means that there is a resistance to pivoting the needle guard into its open position. This has the effect of providing a resilient biasing against pivoting of the needle guard out of its open or closed positions. In

other words, it is necessary to exert a positive pivoting force on the needle shroud to move it from one of its two rest positions, i.e. fully closed and fully opened.

Figures 8A, B, C, D, E and F show a further modification of the embodiment shown in Figure 6A. Again, the same reference numerals are used to indicate corresponding parts. The major difference is that the operating arm 8 is connected to a hinge 32 connected to a forked portion which closes off the base of the open side of shroud 7. In the open position of the shroud shown in Figure 8C, forked portion 33 lies on the shoulder 34 of needle boss 25. Shroud 7 may be resiliently held in this position by ears 35 engaging over sleeve 21. Downward thumb pressure on arm 8 causes the shroud 7 to return to the closed position by forked portion 33 riding over shoulder 34. This downward pressure on arm 8 causes the sleeve 21 to slide downwardly over boss 25 until the shroud snaps back into the closed position. Because needle bosses are normally tapered, sleeve 21 must usually be broken as shown in Figure 8A at 37. The sequence of relative movement between the sleeve 21 and the boss 25 is illustrated in Figures 8D to 8G. This embodiment also includes at 36, (see Figures 8A and 8B), a foam insert in the tip of shroud 7 which is positioned to absorb any drops of blood which may be adhering to the needle tip. If desired, this feature can be included in any of the embodiments.

Figure 9A shows a further embodiment in which the needle shroud 7 is moulded integrally with a needle boss. Although the moulding is a little more complex in this embodiment the mechanics of the hinge movement are better than the arrangement shown in Figures 6A and 7A and for this reason among others it is currently preferred. In Figure 9A, the needle shroud 7 is shown in full lines in an intermediate position, between open and closed positions, in which it is conveniently moulded together with a needle boss and interconnecting hinge. As in all embodiments, the needle is sealingly fixed into the boss, e.g. with adhesive or by heat softening the tip of the boss just prior to packaging the needle/guard assembly. Figure 9A additionally shows in ghosted lines the open and closed positions of the needle shroud. Needle shroud 7 is connected to needle boss 25 by integrally moulded hinge element 40. Because the needle assembly is moulded in its intermediate position, pivoting movement of the shroud in its open position tends to stretch the hinge element and this stress assists the movement of the shroud into its closed position in a smooth action. Also the thumb pressure on the arm 8 is translated into a pulling action, via hinge 40, on the upper end of the needle boss 25. Since the shroud 7 pivots about the heel 41 of the shroud, this action generates a moment equal to approximately the height of the needle boss which is effective in closing the shroud around the needle.

Figure 9B is a perspective view, partially in section and Figure 9C is a similar but full perspective view showing the connection of shroud 7 to the needle boss solely by the integrally-moulded hinge or strap 40. The arm 8 is shown as solid plastic, although it will be appreciated that this could be hollowed somewhat to save material.

In Figure 9D, the same embodiment is shown in its closed position in longitudinal section and giving a better view of the shape of the heel portion 41.

Figures 9E and F are longitudinal sections at two different depths through the needle guard assembly and Figure 9G is a plan view from below. A pair of longitudinal ribs 42 moulded on the outside of the needle boss 25 are clearly apparent in Figures 9F to 9G as well as in Figure 9C. Ribs 42 contact a pair of abutments 43 in the closed position. Abutments 43 are moulded on the inside of shroud 7 and move over ribs 42 when the shroud is pivoted into its open position and accordingly resiliently restrain the shroud in the closed position. An additional pair of abutments 44 are moulded on the inside of the shroud in such a position as to engage ribs 42 when the shroud is in its open position and these resiliently hold the shroud steady until the resistance is overcome by pressure on arm 8 to cause the shroud to close. The pivoting movement of the shroud 7 about the needle boss 25 and the engagement of the abutments 43 and 44 with the ribs 42 in the open and closed positions is

shown more clearly in Figures 9H, 9J and 9K.

Figure 9N is a further side elevation, partly in section, of the embodiment of Figure in its preferred moulding position and Figure 9P is a plan view, seen from below, of Figure 9N. Cross-sectional views taken respectively along the lines 1, 2, 3 and 4 in Figure 9N are illustrated in Figures 9N1, 9N2, 9N3 and 9N4. It will be appreciated from these views that this embodiment can be moulded by using appropriate insert tools, introduced from above and below.

CLAIMS

1. A hypodermic syringe having a needle guard which is pivotable between a first position in which it covers the tip of the needle and a second position in which the needle tip is exposed and the guard lies in a position which does not interfere with the use of the syringe.

2. A syringe according to claim 1 in which the guard includes means for releasably holding it in said first and second positions.

3. A syringe according to claim 1 or claim 2 in which the guard comprises a generally trough-shaped shroud which is adapted to shroud the needle on three sides and to protect the tip in said first position and in which the shroud is pivotably mounted at the base of the needle so that on pivoting the shroud from said second to said first position, the needle enters the open side of the trough-shaped shroud.

4. A syringe according to claim 3 in which the shroud is pivoted between the second and first positions by finger pressure applied to a lever extension portion of said guard.

5. A syringe according to any one of the preceding claims in which the needle guard is moulded integrally with a boss for supporting the needle or with a sleeve which is adapted to be fitted over a needle boss.

6. A syringe according to claim 5 in which the needle guard is connected to the needle boss or to said

sleeve by a flexible, integrally moulded strap.

7. A syringe according to claim 6 wherein said strap connects said lever extension portion of the guard to the needle boss or sleeve and wherein flexing of the strap allows the guard to pivot between said first and second positions.

8. A needle assembly for a syringe which comprises a needle boss having a needle projecting therefrom, a needle guard integrally attached to the needle boss by a flexible strap, said guard including a shroud portion which, in a first position, is capable of protecting the needle tip and in a second position, allows the needle to be used with a syringe, the flexible strap permitting the shroud portion to be pivoted from said first position to said second position and vice versa.

9. A needle assembly according to claim 9 in which said flexible strap connects the needle boss to a lever arm portion of said needle guard.

10. A needle assembly according to claim 9 or 10 which includes integrally moulded abutment means on said guard and/or on said boss.

Figure 1

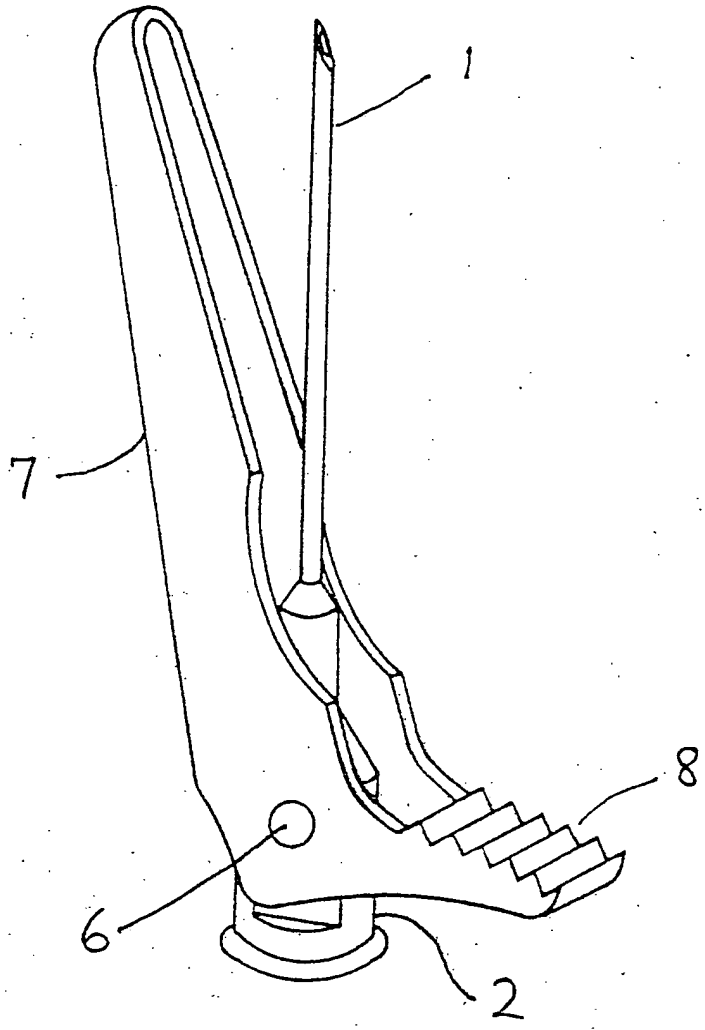


Figure 2

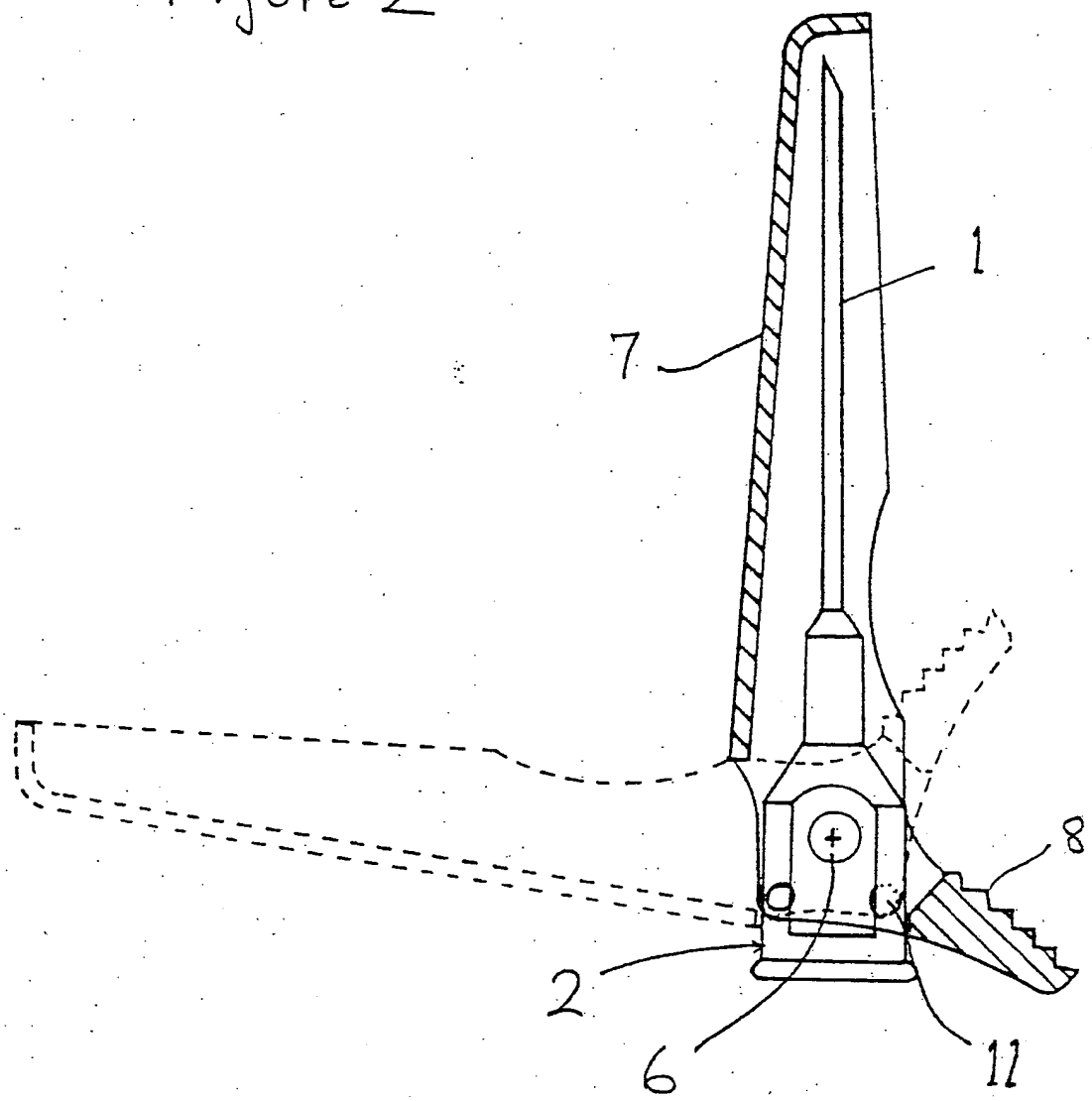


Figure 4

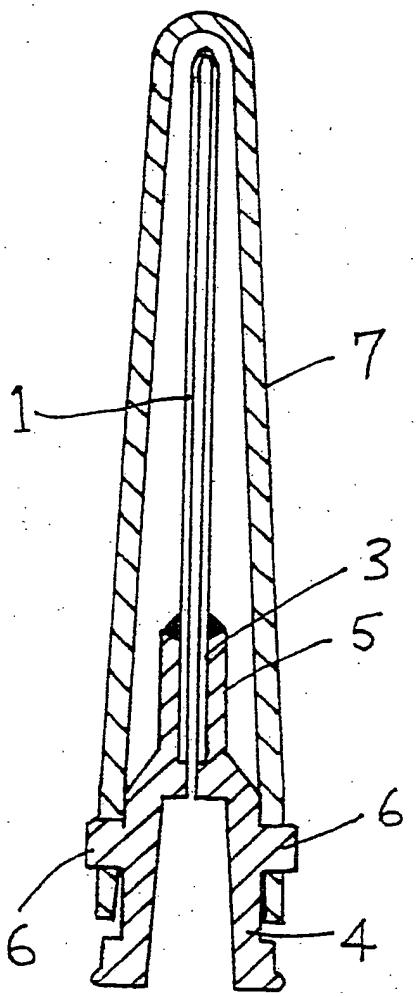


Figure 3

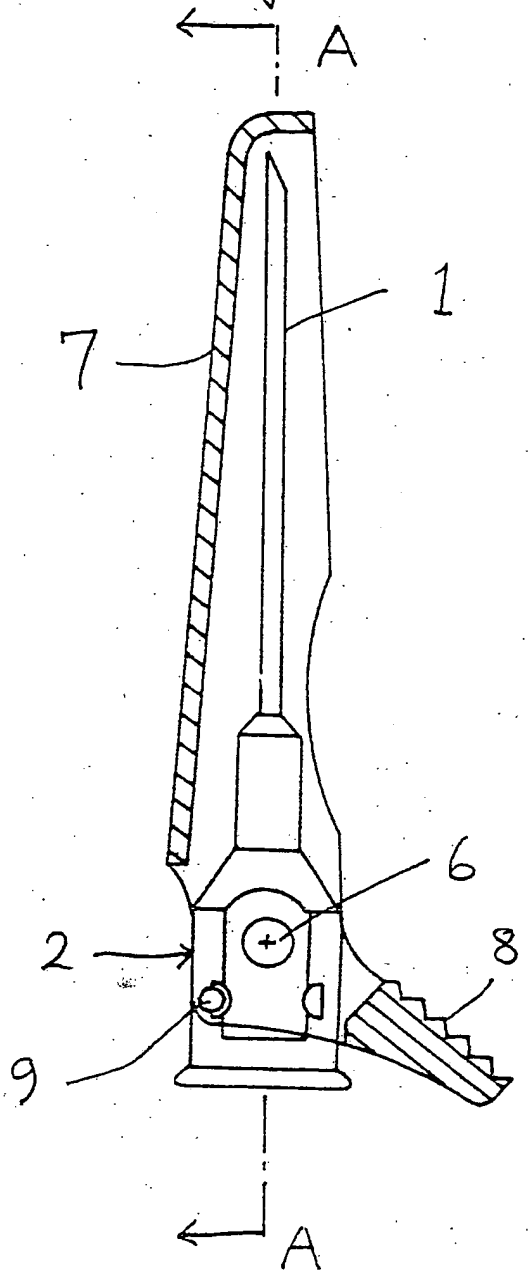


Figure 5

Figure 5A

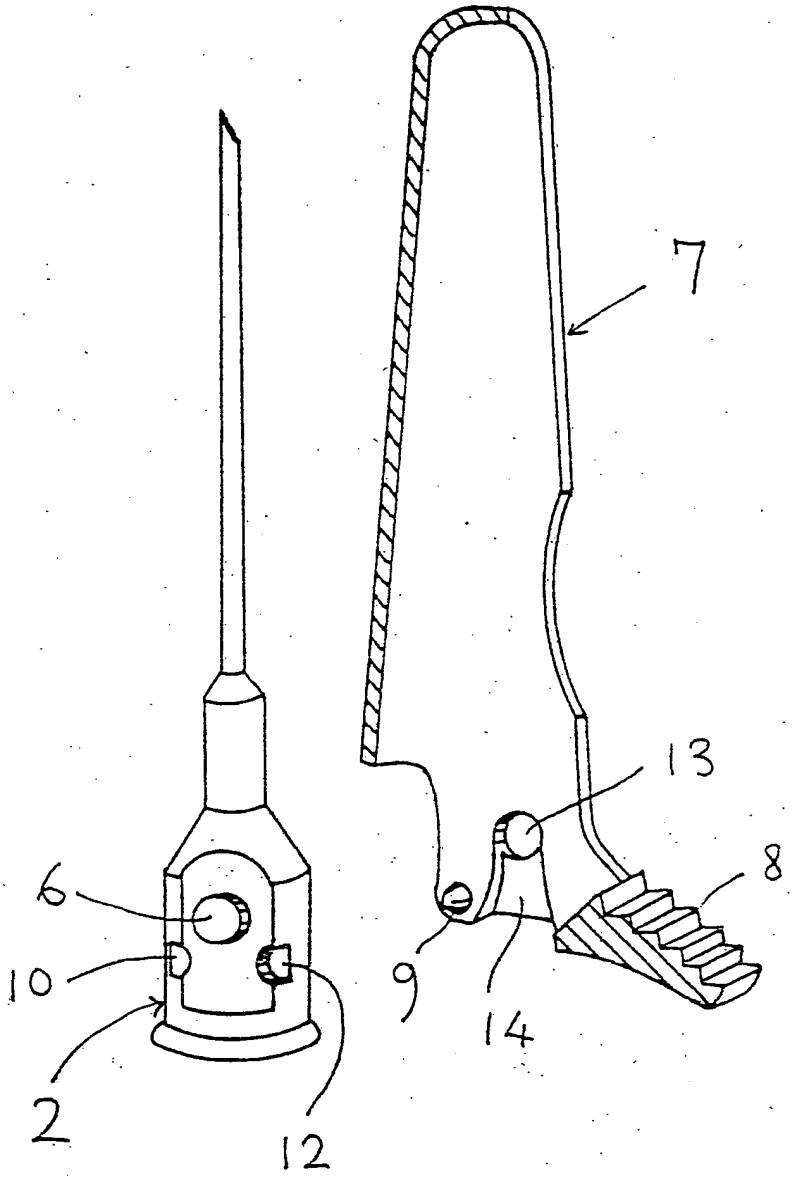


Figure 6A

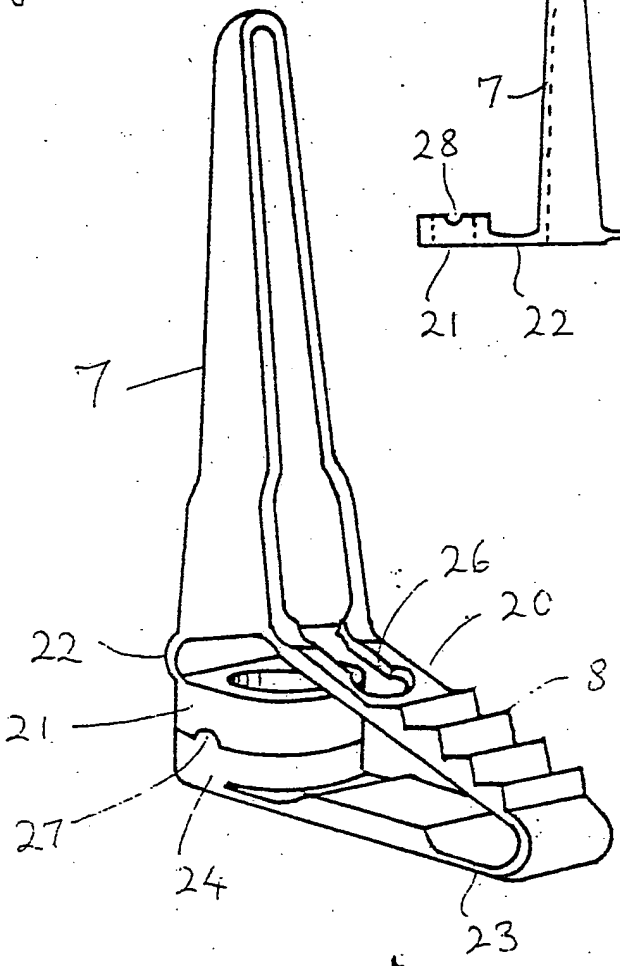


Figure 6D

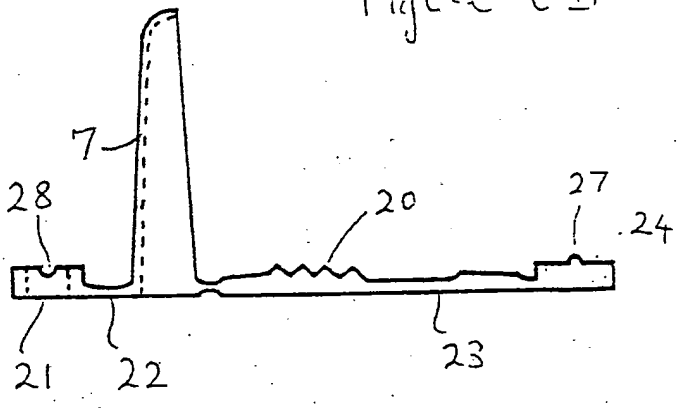


Figure 6B

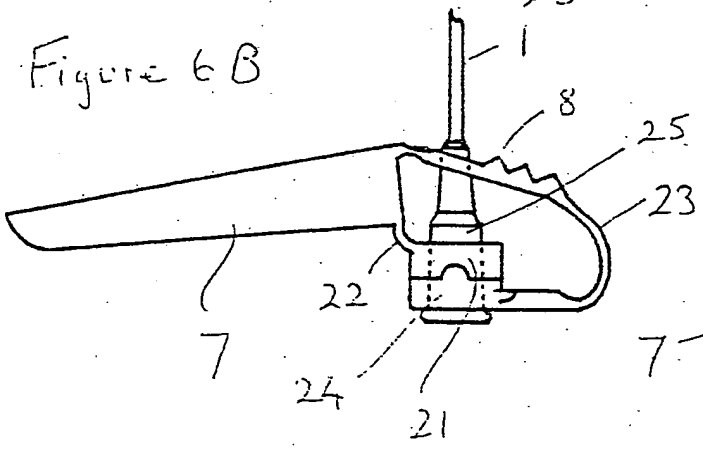


Figure 6C

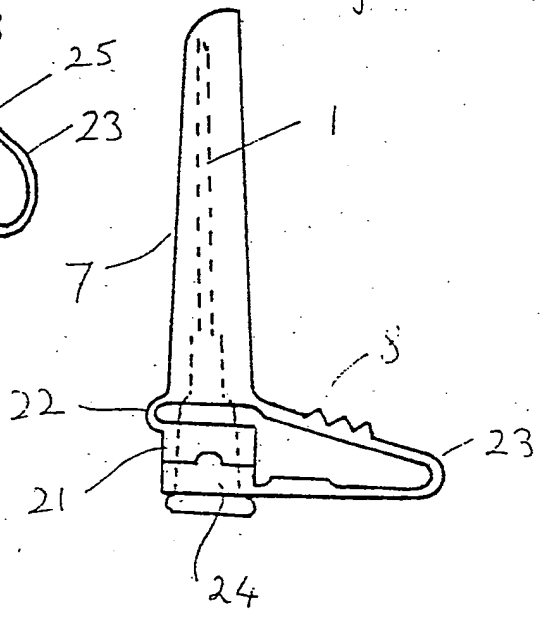


Figure 7A

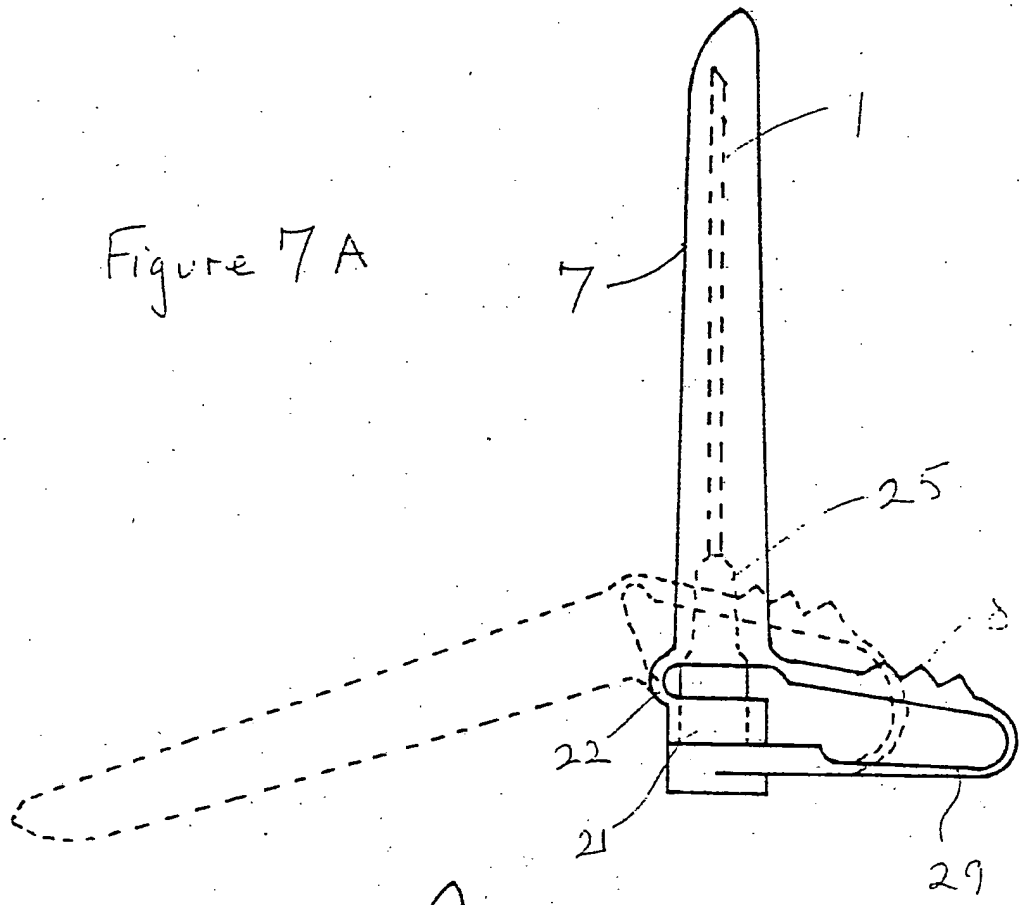


Figure 7B

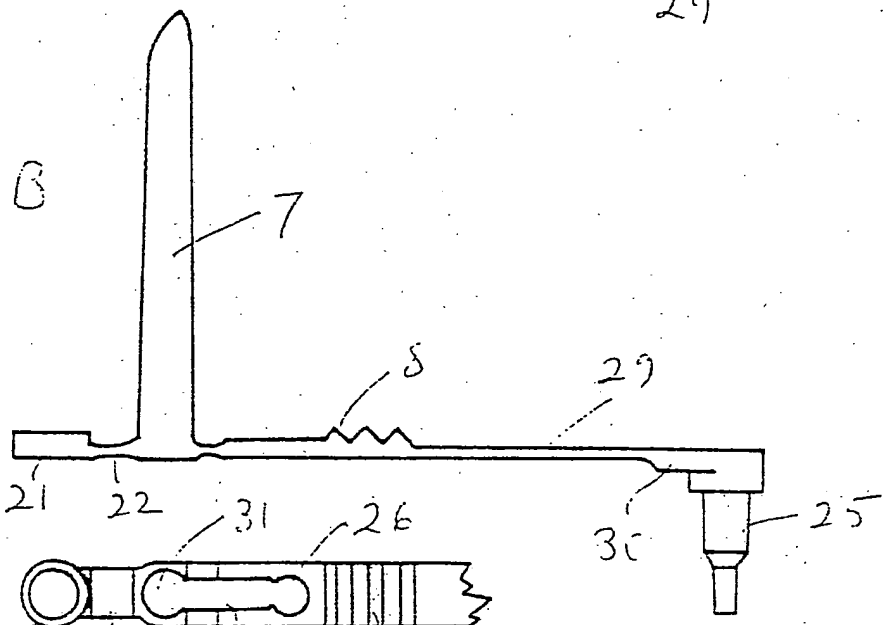


Figure 7C

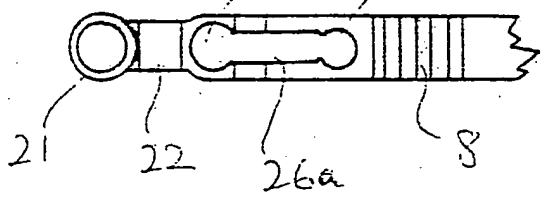


Figure 8A

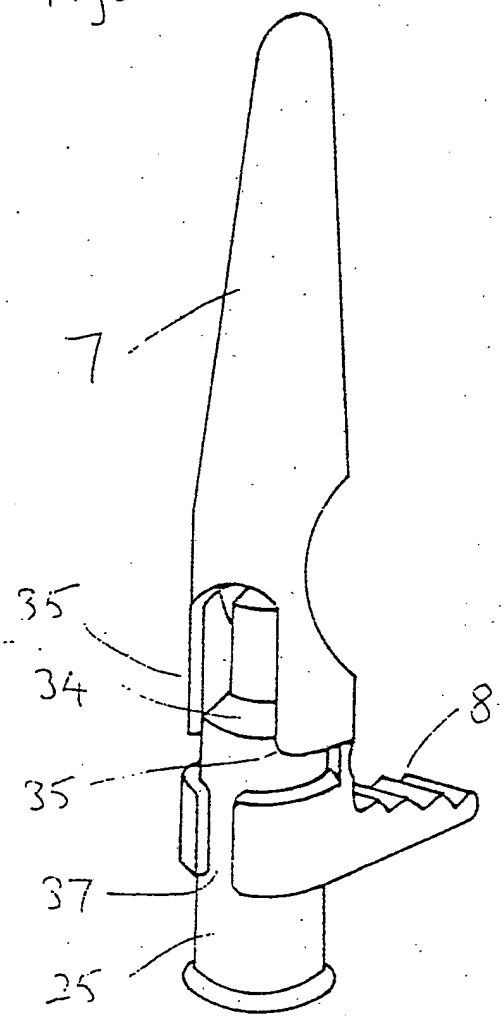


Figure 8B

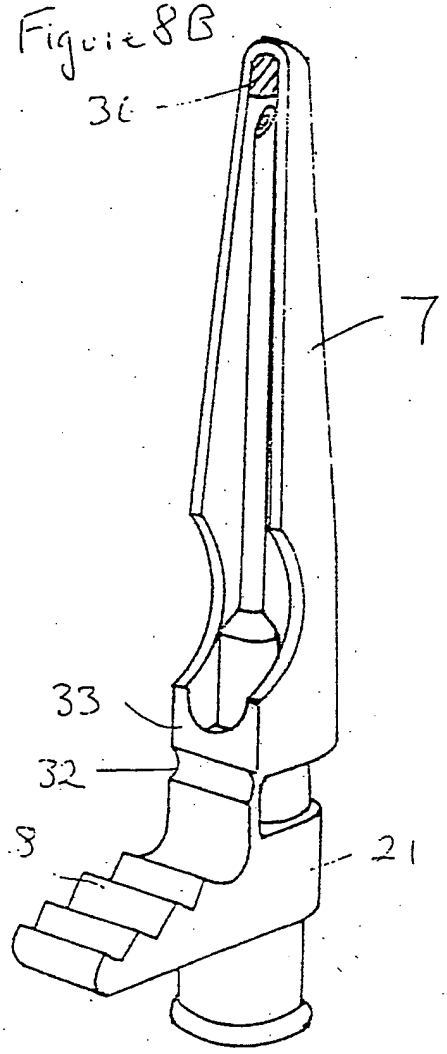


Figure 8C

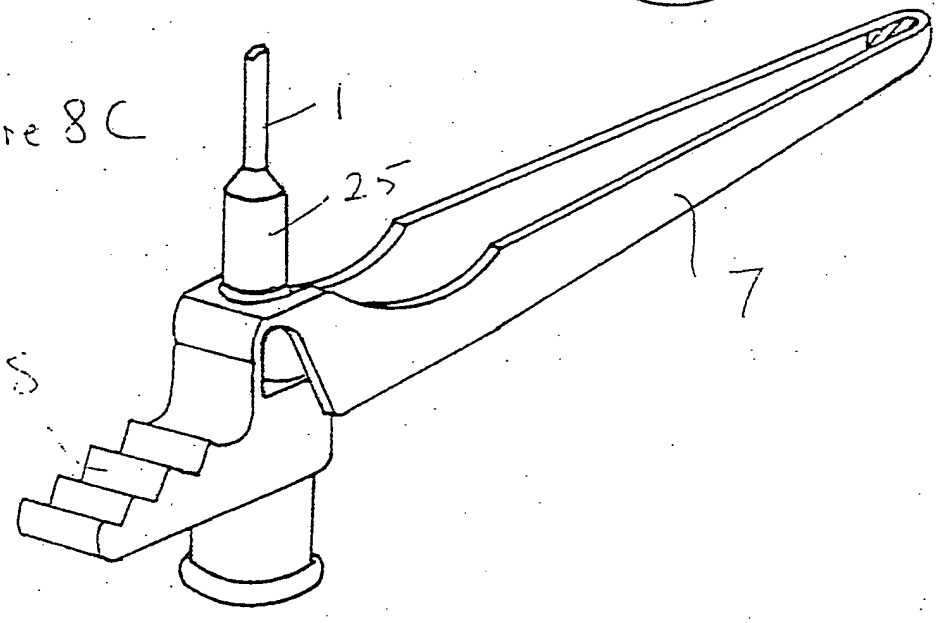


Figure 8D

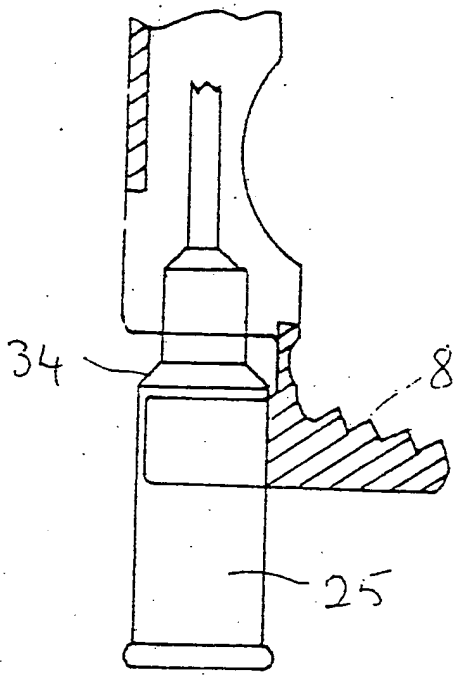


Figure 8E

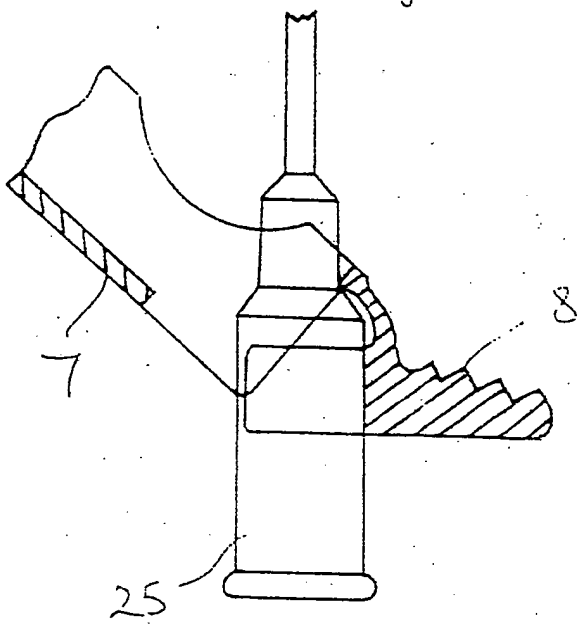


Figure 8F

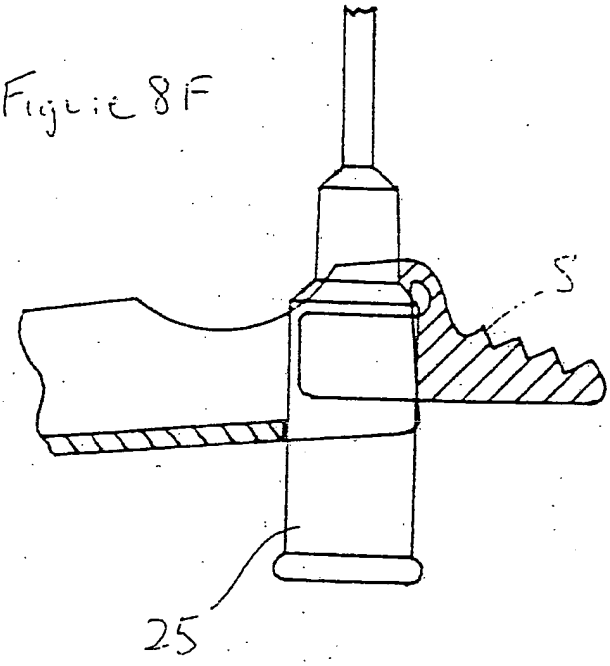


Figure 8G

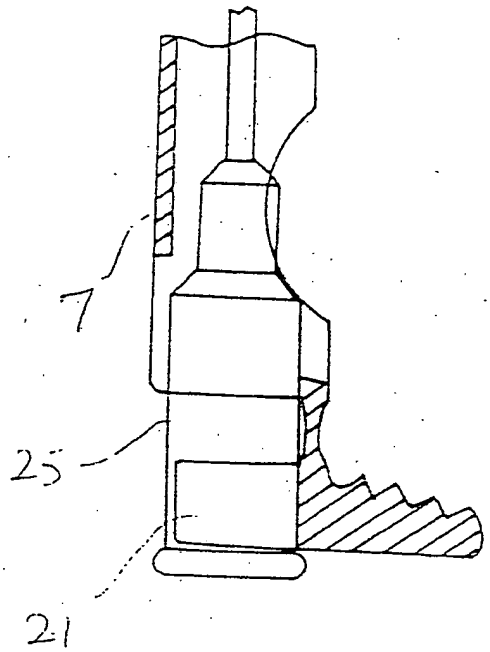


Figure 8D

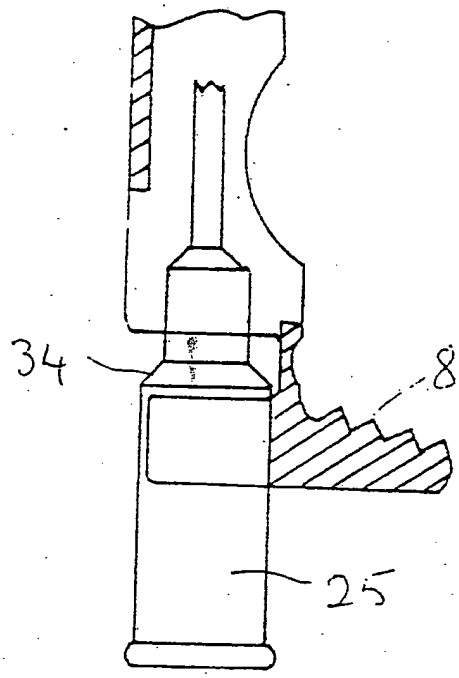


Figure 8E

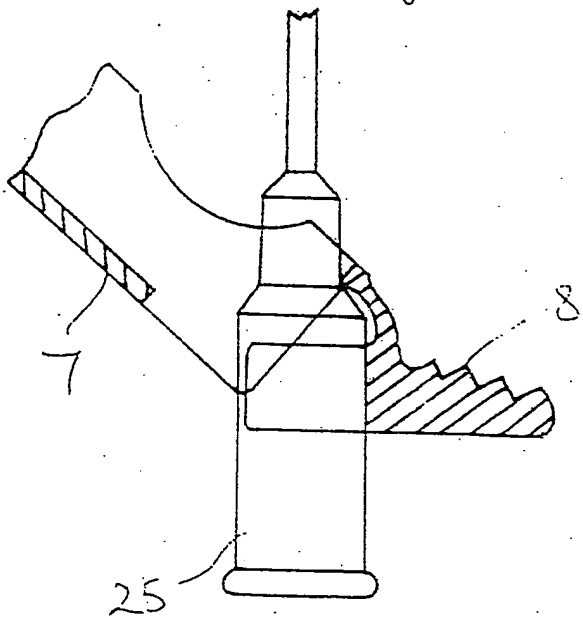


Figure 8F

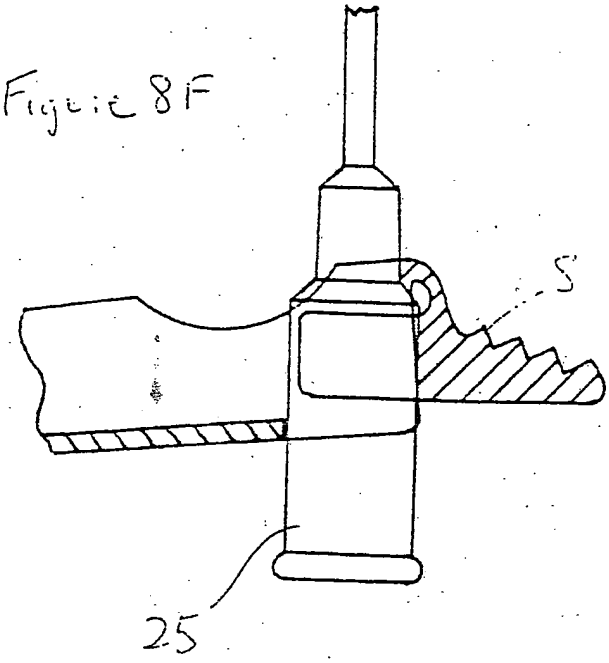


Figure 8G

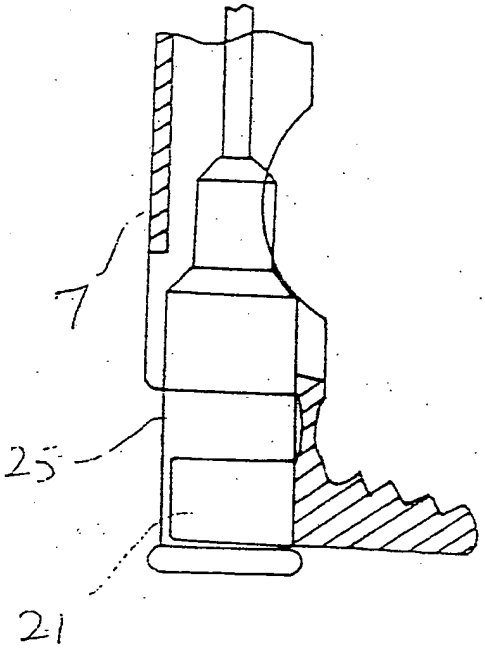


Figure 9A

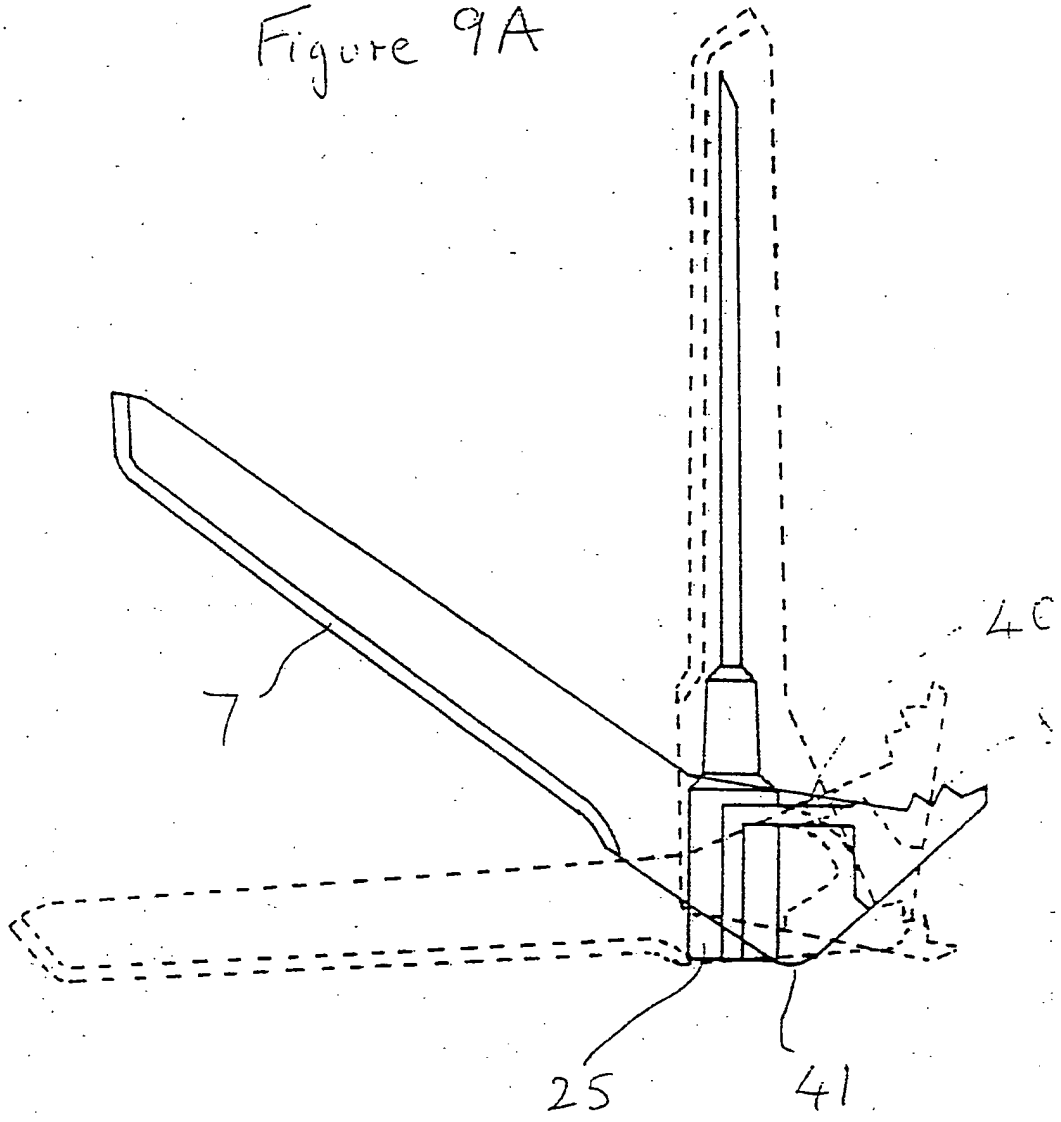


Figure 9B

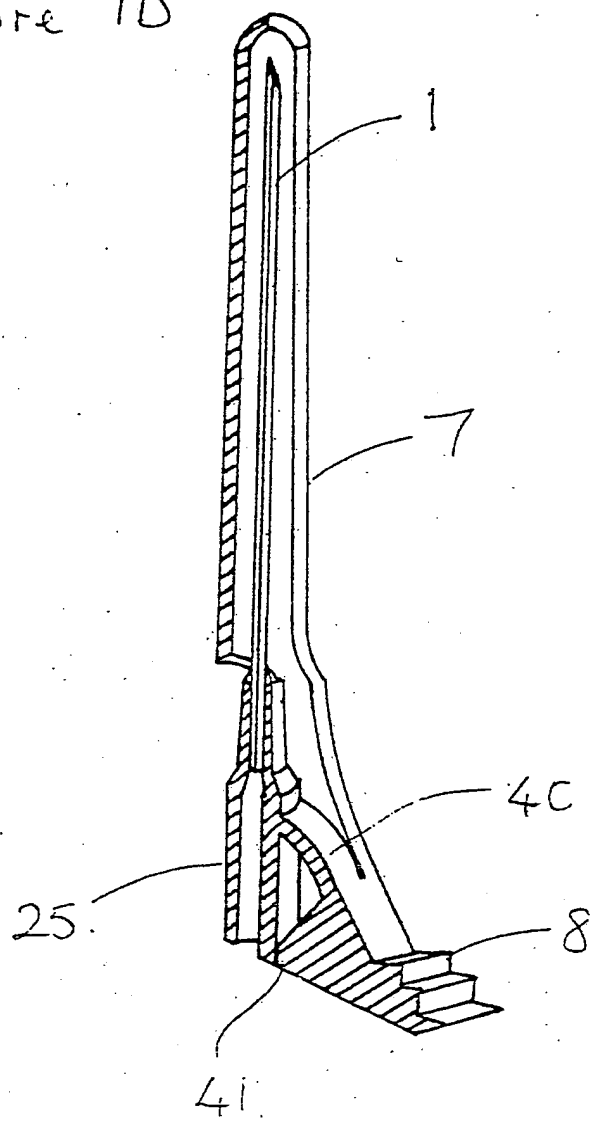


Figure 9C

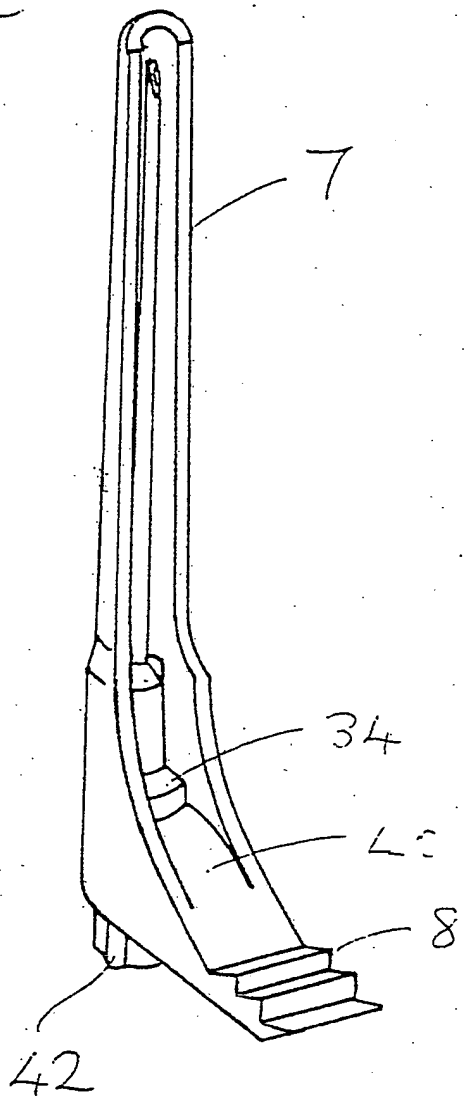


Figure 9D

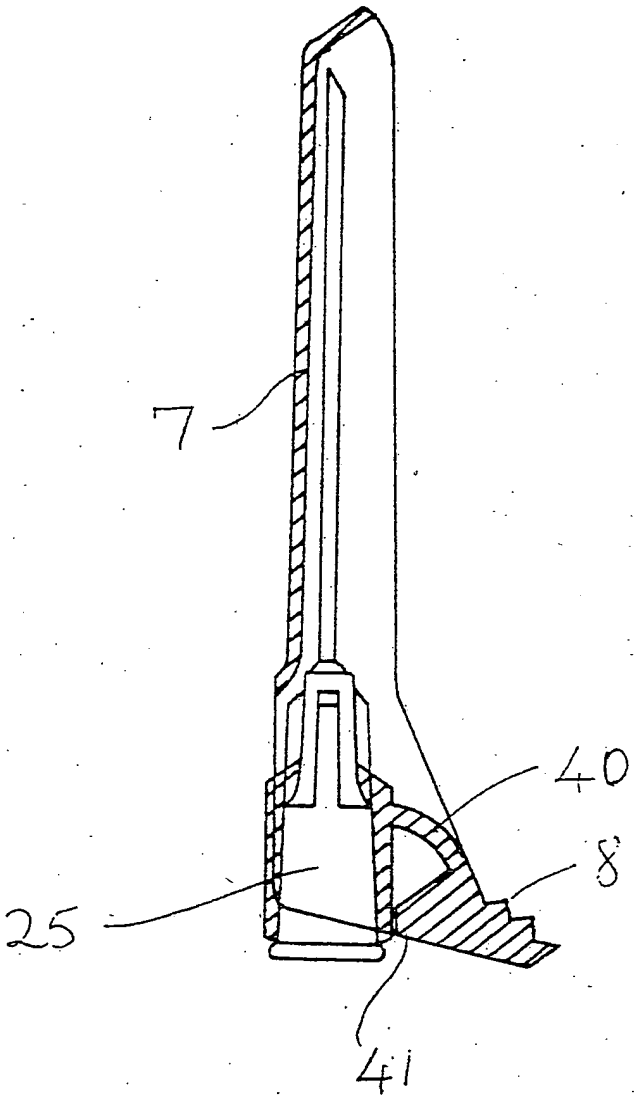


Figure 9E

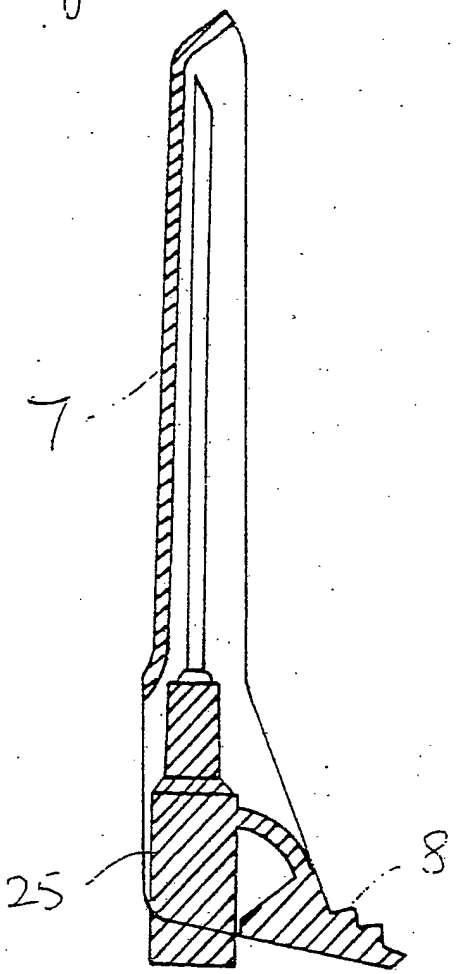


Figure 9F

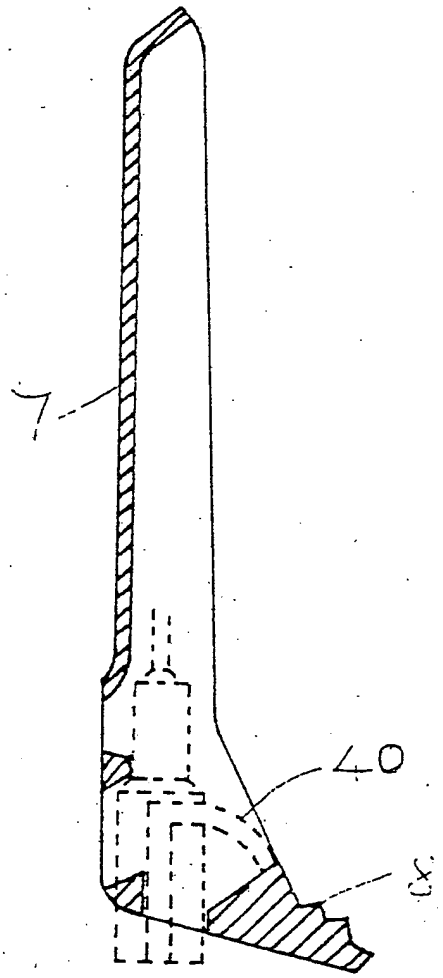


Figure 9G

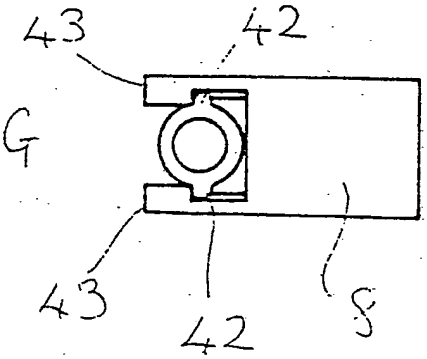


Figure 9H

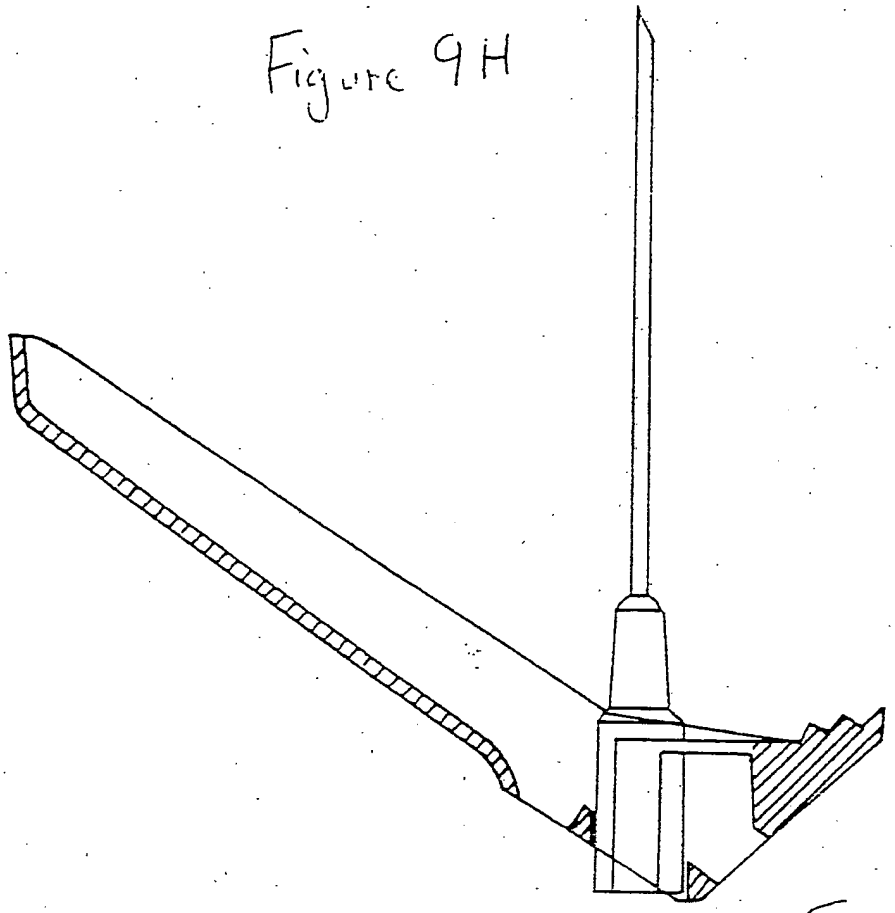


Figure 9J

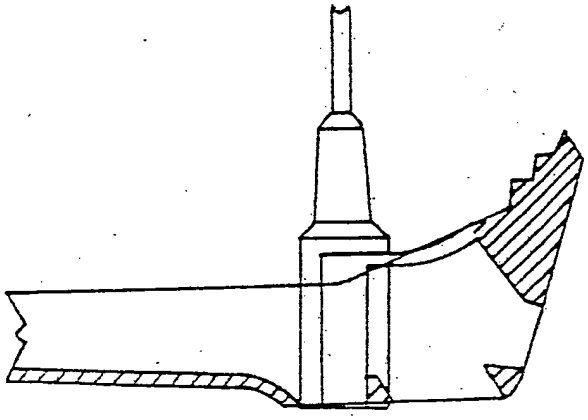
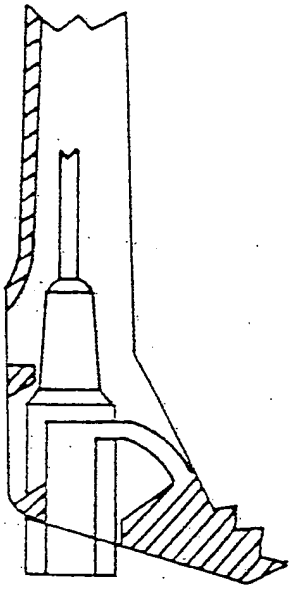


Figure 9K



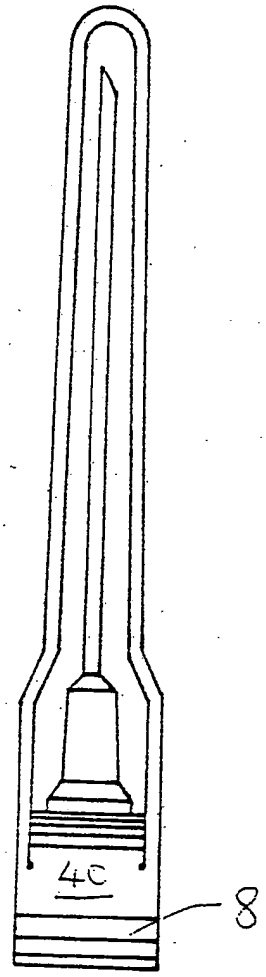


Figure 9L

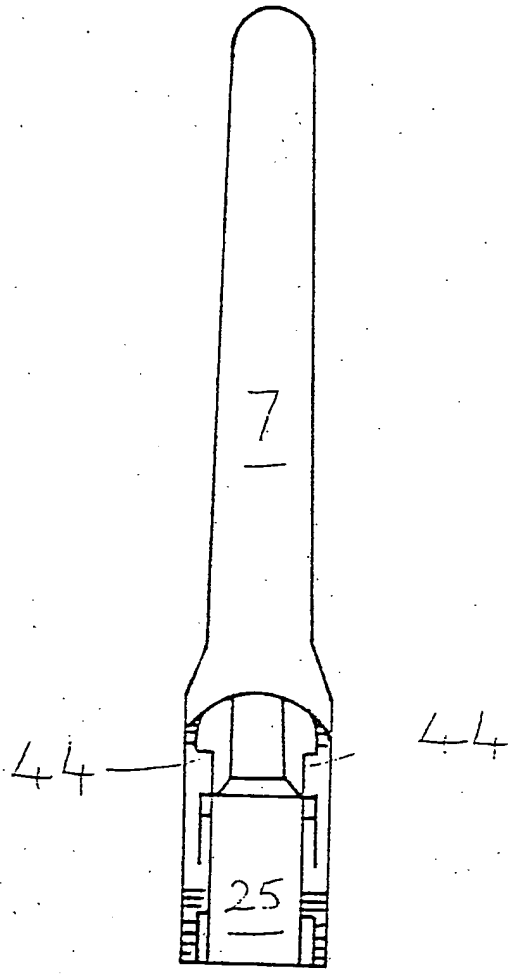


Figure 9M

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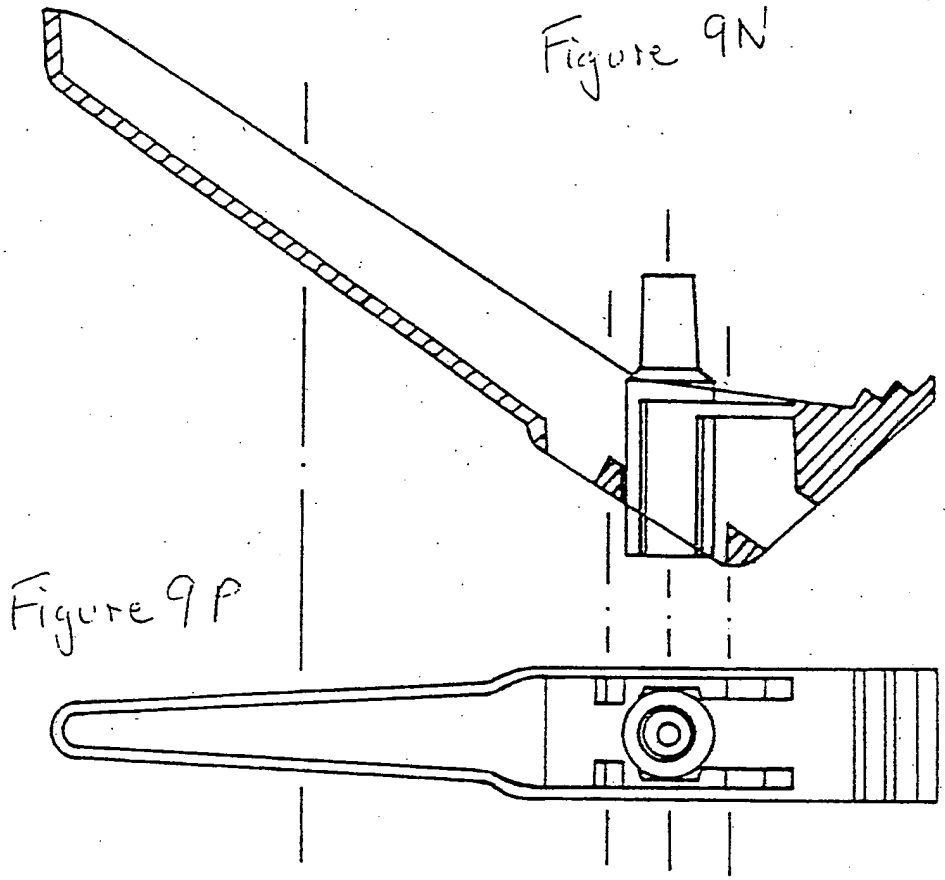

Figure 9N

Figure 9P

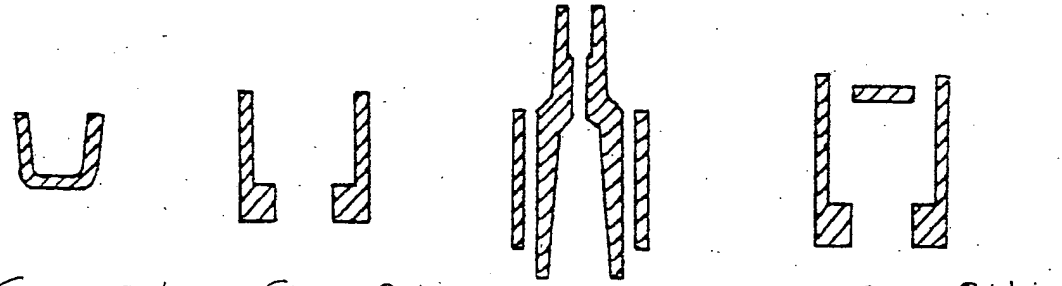

Figure 9N1 Figure 9N2 Figure 9N3 Figure 9N4

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 89/00837

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[5]: A 61 M 5/32

II. FIELDS SEARCHED

Minimum Documentation Searched 7

Classification System	Classification Symbols
IPC[5]:	A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched 8

III. DOCUMENTS CONSIDERED TO BE RELEVANT 9

Category *	Citation of Document, 11 with indication, where appropriate, of the relevant passages 12	Relevant to Claim No. 13
P,X	FR, A, 2618685 (BRUNET) 3 February 1989, see the whole document	1
A		2-10
	--	
X	WO, A, 87/07162 (THURECHT et al.) 3 December 1987, see claims 1-5; figures	1,3,5,6,8,10
Y		2,4
	--	
X	DE, U, 8705966 (ALMO ERZEUGNISSE ERWIN BUSCH GMBH) 25 June 1987, see page 6, line 5 - end; figures 8-10	1,3-6,8,10
	--	2
Y	US, A, 4681567 (MASTERS et al.) 21 July 1987, see abstract; figures 1,2	2
A		10
	--	
Y	FR, A, 1098727 (ANAVE) 18 August 1955, see page 2, column 2, lines 6-8; figure	4
	--	
X	US, A, 3658061 (HALL) 25 April 1972, see claims 1-4; figures	1,3,5,6,8
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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
17th November 1989	12. 12. 89
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	T.K. WILLIS

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document with indication, where appropriate, of the relevant passages	Relevant to Claim No
X	US, A, 4747836 (LUTHER) 31 May 1988, see abstract; figures	1,3

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 8900837 SA 30461

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 04/12/89
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A- 2618685	03-02-89	None	
WO-A- 8707162	03-12-87	AU-A- 7487887	22-12-87
		EP-A- 0267947	25-05-88
DE-U- 8705966	25-06-87	None	
US-A- 4681567	21-07-87	None	
FR-A- 1098727		None	
US-A- 3658061	25-04-72	None	
US-A- 4747836	31-05-88	US-A- 4838871	13-06-89